Mentor Sterile Saline Mammary Volume Sizers
510(k) Notification

APR 2 3 2001

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K010709

Contact Person: Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

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Date Prepared: March 8, 2001

Device Name and Classification

Proprietary Name:	Mentor Sterile Saline Mammary Volume Sizer
Common Name:	Sizer
Classification Name:	Not Classified
Product Code:	Unknown

Manufacturer

Mentor Texas
3041 Skyway Circle North
Irving, TX 75038

Device Description

The Mentor Sterile Saline Mammary Volume Sizer (Sizer) is a silicone elastomer device designed for temporary intraoperative placement in the surgically prepared mammary pocket. The Sizer is used to evaluate the appropriate mammary prosthesis volume for each patient prior to implantation of a mammary prosthesis. The Sizer is inflated to its optimal volume with saline after it is placed within the pocket, and then deflated prior to its removal.

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Substantial Equivalence Claim

The Mentor Sterile Saline Mammary Volume Sizer is substantially equivalent in material, function, performance and design to the mammary sizers manufactured and marketed by Mentor Corporation (Pre-amendment device) and Specialty Surgical Products Inc., 510(k) No: K984106.

Indications for Use

The Mentor Sterile Saline Mammary Volume Sizer is only indicated for the single use for temporary insertion intraoperatively to evaluate the volume of the mammary prosthesis to be implanted.

Summary of Testing

There as no Domestic or International Test specifications for mechanical testing of volume sizers. All mechanical testing specifications are established internally. All biocompatibility testing requirements are established per ASTM F748, ANSI/AAMI 10993-1 and Mentor SOP-HS-136, "Material Qualification: Biocompatibility Testing".

Mechanical Testing

Test	Test Standard
Shell Tension Set	≤ 10% stretch after 300% elongation for 3 minutes & relax for 3 minutes.
Shell Break Strength	≥2.5 lbs.
Device Inflation/Overexpansion	200% Inflation of maximum recommended volume held for 10 minutes.
Tubing to Patch Joint Strength	>1.5 lbs.
Device Leakage	Submerge in 70% IPA, no leakage.
Shell to Patch Joint Strength	200% for 10 seconds

Biocompatibility Testing

Test	Test Standard
Cytotoxicity	Non-cytotoxic (ASTM F478, ANSI/AAMI 10993-1 & SOP-136)
Hemolysis	Non-hemolytic (SOP-HS-136)
Implantation	Short-term - Non-toxic (SOP-HS-136)
Intracutaneous Toxicity	Non-toxic (ASTM F748 & SOP-HS-136)
Systemic (Acute) Toxicity	Non-toxic (ASTM F748 & SOP-HS-136)
Sensitization	(ASTM F748 ANSI/AAMI 10993-1 & SOP-HS-136)
Irritation	(ANSI/AAMI10993-1 & SOP-HS-136
Mutagenicity	Non-mutagenic (ASTM F478 & SOP-HS-136)
Pyrogenicity	Non-pyrogenic (ASTM F748 & SOP-HS-136)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2001

Ms. Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, California 93111

Re: K010709
Trade/Device Name: Mentor Sterile Saline Mammary Volume Sizers
Regulation Number:
Regulatory Class: Unclassified
Product Code: MRD
Dated: March 8, 2001
Received: March 9, 2001

Dear Ms. Crawford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Mentor Sterile Saline Mammary Volume Sizers
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510(k) Number (if known): K010709

Device Name: Mentor Sterile Saline Mammary Volume Sizers

Indications for Use:

The Sizer is only indicated for single use for temporary insertion intraoperatively to evaluate the volume of the mammary prosthesis to be implanted.

The Mentor Sterile Saline Mammary Volume Sizer is intended strictly for the sizing of Mentor mammary implants, and not for use with any other prostheses or implants.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over the Counter Use _____
(Per CFR 801.109)

(Optimal Format 1-2-96)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010709